

REMARKS

Applicants have herewith amended claims 5-7 to address a spelling error, replacing the erroneous “hydroxyapatite” with the corrected “hydroxylapatite”. In a further effort to expedite prosecution, Applicants have amended 2 to specify the use of “flow” or “non-binding” HA chromatography to purify wild-type von Willebrand factor (VWF) from a plasma fraction. More particularly, Applicants have replaced the allegedly vague reference to VWF being “substantially not bound” with the more precise requirement that the HA matrix bind “less than 10% of the wild-type VWF contained in the fraction”. Support for the new language is found in the specification as originally filed, particularly at page 4, lines 7-9. Accordingly, Applicants submit that no new matter has been added. However, Applicants reiterate that the amendments herein are presented solely for the purpose of expediting prosecution and should not be construed as Applicants’ agreement with or acquiescence to the grounds of rejection previously set forth.

Applicants submit that the present amendments place the instant application in condition for allowance and thus respectfully petition for the entry thereof, the withdrawal of all outstanding grounds of rejections, and the issuance of a timely notice of allowance in view of the following remarks:

Double Patenting

In the Final Office Action of September 13th, the Examiner maintained the rejection of claims 2, 4-18, and 24 on the grounds of obviousness-type double patenting over co-pending U.S. Application No. 10/594,453. While Applicants disagree with the Examiner’s characterization of the overlapping subject matter and his suggestion of obviousness, Applicants nevertheless include herewith a duly executed terminal disclaimer over the ‘453 Application. However, Applicants wish to reiterate that the terminal disclaimer and accompanying claim amendments submitted herewith are presented solely for the purpose of expediting prosecution and should not be construed as Applicants’ agreement with or acquiescence to the grounds of rejection previously set forth or subsequently suggested.

Rejections under Section 102 – Anticipation

Claims 2, 5-6, 14, and 24 stand finally rejected under 35 U.S.C. § 102(b) as being anticipated by Gorman or Dumas, for reasons of record. According to the Examiner, the phrase “substantially not bound” may be broadly construed to encompass any degree of binding or non-binding. As such, the Examiner finds the methods of Gorman and Dumas to anticipate the invention of the pending claims.

It appears that quantifying the degree of binding (or lack thereof) would overcome this rejection. As noted above, Applicants have replaced the phrase “substantially not bound” with the more precise requirement that the HA matrix bind “less than 10% of the wild-type VWF contained in the fraction”. In contrast, Gorman and Dumas describe the purification of VWF or a fragment thereof using binding chromatography, a process wherein a VWF-containing sample is loaded on (and bound to) an HA column and then subsequently eluted with a potassium phosphate buffer gradient (Gorman) or a HEPES gradient (Dumas). Accordingly, since neither Gorman nor Dumas disclose or suggest restricting the binding between VWF and HA to “less than 10%”, Applicants respectfully submit that they cannot be fairly characterized as anticipating the invention of the pending claims. As such, reconsideration and withdrawal of the rejection is warranted.

As an additional matter, Applicants respectfully disagree with the Examiner’s suggestion that the claim recitation of “wild-type” VWF does not adequately exclude the “wild-type A1 domain of VWF” targeted by Dumas. As evidenced by the dictionary citations provided herewith, the phrase “wild-type” is accepted in the art as referring to the phenotype of the typical form of a species as it occurs in nature. Since the Dumas fragments are not found in nature but rather are necessarily the product of recombinant techniques and genetic engineering, they cannot be fairly characterized as “wild-type”. For this additional reason, Dumas cannot be fairly characterized as anticipating the presently claimed invention.

Rejections under Section 103 – Obviousness

The Examiner further rejected the pending claims on the following obviousness grounds:

- Claims 2, 4-6, 14-17 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Burnouf-Radosevich or Newman in view of Labrou, Dumas and Zardi (a 5 reference combination);
- Claims 18 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the above 5-way combination, further in view of Winkelman and Ichitsuka (i.e., a 7 reference combination); and
- Claims 7-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the above 7-way combination, further in view Marshak and Schroder.

In the context of obviousness, the Examiner reiterated his position on the proper interpretation of the phrases “substantially not bound”, “unbound VWF”, and “wild-type VWF” and further dismissed Applicants’ challenges to motivation as “unpersuasive”. Nevertheless, it is readily apparent that none of the nine cited references, alone or in combination, teach the purification of wild-type VWF from a plasma fraction using “non-binding” or “flow” HA chromatography, a process characterized the binding of “less than 10% of the wild-type VWF contained in the fraction” to the HA matrix. Accordingly, Applicants respectfully petition for reconsideration and withdrawal of outstanding obviousness rejections in view of the amendments and remarks herein.

CONCLUSION

In view of the above, Applicant respectfully submits that claims 2, 4-18, 20, and 24 are in condition for allowance and respectfully request an early notification of such.

Applicants respectfully submit that this response is timely and no fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to our Deposit Account No. 50-2101.

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If the Examiner has any questions or concerns regarding this communication, he is invited to contact the undersigned.

Respectfully submitted,

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